Appendix B: **Information Insurance**

Multicenter, randomized non-inferiority trial of early treatment versus expectative management of patent ductus arteriosus in preterm infants.

Radboud UMC has taken out an insurance for the subjects in this clinical trial. This insurance covers losses caused by death or injury resulting from participation in the clinical trial, which reveals itself during the participation of the subject in the clinical trial or within four years thereafter. The personal injury is deemed to have revealed itself at the time it is reported to the insurer.

In the event of a claim, you may contact the insurer directly.

The insurer of the clinical trial is:
Onderlinge Waarborgmaatschappij Centramed B.A.
P.O. Box 7374
2701 AJ Zoetermeer, The Netherlands
Tel.: +31 70 3017070
Email: schade@centramed.nl

The insurance provides a maximum cover of € 650,000 per subject and € 5,000,000 for the entire research, and € 7,500,000 per annum for all examinations of the same client.

The above amounts are included in the “Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen”. Information on this “besluit” can be found at the website of the Central Committee Clinical Trials involving Humans: www.ccmo.nl.

The insurance covers losses resulting from clinical trials.
The insurance does not cover:

- Claims for injury that is inevitable or practically inevitable, given the nature of the clinical trial;
- Injury to the health which also would have occurred if you had not participated in the clinical trial;
- Injury caused by the subject's non- or partial adherence to the directions or instructions;
- Injury to the descendent(s), as a result of an adverse effect of the clinical trial on the subject or on the subject’s descendent(s);
- Injury caused by an existing treatment method in a research into existing treatment methods;
- Injury resulting from the occurrence of a risk of which the subject was warned in the written information, unless the risk occurs in a more serious degree than was expected or said risk was highly unlikely to occur